from the requirements of section 502(l) and from the certification requirements of section 512(n) of the act if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use; or in law enforcement; or in research not involving clinical use; or in chemical analysis or physical testing, provided they are to be used only for such instruction, law enforcement, research, analysis, or testing, and provided further that their labels bear the statement ''Not for drug use.''

§ 433.25 [Reserved]

§ 433.26 Neomycin sulfate ointment intended for hypersensitivity testing.

Neomycin sulfate ointment subject to sections 502(l) and 507 of the act and packaged for use as an allergen for skin patch testing of hypersensitivity shall be exempt from the certification requirements of section 502(l) and 507 of the act if it complies with all the following conditions:

(a) It contains neomycin sulfate equivalent to 200 milligrams of neomycin per gram in petrolatum.

(b) The neomycin sulfate used in preparing the neomycin sulfate ointment conforms to the standards prescribed by §444.42(a)(1) of this chapter except §444.42(a)(1)(ii).

(c) The shipment of neomycin sulfate is made as a result of a specific request made to the manufacturer or distributor by a practitioner licensed by law to administer such drug, and the use of neomycin sulfate ointment for patch testing is not promoted by the manufacturer or distributor.

(d) Each package shall bear on its outside wrapper or container and on the immediate container, in addition to other labeling information required by the act and regulations, the following statements in lieu of adequate directions for use:

(1) The statement, ''Caution: Federal law prohibits dispensing without prescription''.

(2) The statement, ''For use only in patch testing''.

(3) The potency of the ointment.

(4) The expiration date as prescribed by §432.5(a)(3) of this chapter.

(e) The quantity shipped is limited to an amount reasonable for the purpose of patch testing in the normal course of the practice of medicine and is used solely for such patch testing.

(f) The manufacturer or distributor maintains records of all shipments for this purpose for a period of 2 years after shipment and will make them available to the Food and Drug Administration upon request.

[43 FR 11151, Mar. 17, 1978]

Subpart D—Records and Reports

§ 433.30 Records retention.

At the option of the person having control of records required to be kept by any regulation in this part 433, photostatic or other permannnt reproductions may be substituted for such records after the first 2 years of the holding period.

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

Sec.